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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,581	01/18/2002	Syed Riauddin Hashmi	455.1005	6351

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EXAMINER	
WANG, SHENGJUN	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 09/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/031,581	HASHMI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 22-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 22-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of applicants' remarks submitted September 3, 2004 is acknowledged. Since Croft reference (GB 2347349) is not a prior art, the final rejections set forth in the prior office action is herein withdrawn in favor of the following rejections,

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al (NZ 270754, IDS) in view of Dupont et al. (6,028,1 18).

The instant invention is directed toward a composition comprising at least one anti-inflammatory agent selected from green-lipped mussel extract or shark cartilage, and at least one enhancing agent selected from a bark product, a bark extract, or shark cartilage, wherein for a composition including just one member from each group, the selected members must be different.

McFarlane et al teaches an anti-inflammatory composition comprising. New Zealand green-lipped mussel extract and a fish oil, particularly useful for treating arthritis. The composition has synergistic effect as compare the individual ingredients therein. See the entire documents

McFarlane et al. does not teach expressly a composition comprising both green-lipped mussel extract and Shark cartilage.

However, Dupont et al. teach a method of treating arthritis by administering an extract of shark cartilage. The shark cartilage is taught as having anti-angiogentic and anti-inflammatory activities. See Col. 28, lines 48-56.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to make an composition useful for treating arthritis comprising both green-lipped mussel extract and shark cartilage.

A person of ordinary skill in the art would have been motivated to make an composition useful for treating arthritis comprising both green-lipped mussel extract and shark cartilage because it is prima facie obvious to combine two compositions each of which is taught in the prior art to be useful for same purpose in order to form third composition that is to be used for very the same purpose; idea of combining them flows logically from their having been individually taught in prior art; See In re Kerkhoven, 205 USPQ 1069. Additionally, it would have been obvious to add the shark cartilage extract of Dupont et al. to the composition of McFarlane because of the expectation of enhancing blood flow to the suffering area. Further, making a therapeutical composition into a well-known form, such as tablet, capsule, is within the skill of artisan. Finally, a therapeutical agent broadly known to be useful for treating arthritis, would have reasonably expected to be useful for both human and non-human animals.

Claims 12, 26, 27, 29, 30, are rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al. in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Henderson et al. (6,255,295).

McFarlane and Dupont are applied as discussed above. The references lack preferred additional pharmaceutically active agents.

However, Henderson et al. teach compositions for the treatment, protection, repair, and reduction of inflammation of connective tissue for conditions such as arthritis. Chondroitin sulfate is taught for use in combination with glucosamine for the treatment of osteoarthritis. The compound inhibits the degradative enzyme that break down connective tissue, thereby promoting the maintenance of healthy connective tissue. Vitamins B12 and B6, folic acid, dimethylglycine, trimethylglycine, and others are taught as ingredients that augment the function of S-adenosymethionine, which promotes the production of connective tissue matrix, and are taught as likely to be lacking in patients suffering from connective tissue disorders. It is taught that compositions that treat inflammation of connective tissue can be administered to humans or animals. See abstract; Col. 3, line 58-Col. 4, line 12, Col. 6, lines 44-56.

Therefore, it would have been obvious to one of ordinary skill in the art a! the time the invention was made to add vitamin B12, as taught by Henderson, to the composition of the combined references because of the expectation of promoting the production of connective tissue matrix.

Claims 9, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al. in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Church (Velvet Antler: It's Historical Medical Use).

McFarlane and Dupont et al. are applied as discussed above. The references lack deer velvet.

Church teaches that in 1996, researchers at the University of Alberta demonstrated that glycosaminoglycans in the water soluble fractions of velvet antlers have growth promoting effects on cells, and anti-inflammatory properties. See "Review of Scientific Literature on Elk Velvet Antler"

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add deer velvet, as taught by Fisher et al, to the composition of the combined references because of the expectation of achieving a composition that further combats the inflammatory response, thereby easing arthritis.

Claims 7, 8, 25 are rejected under 35 U.S.C. 103(a) ms being unpatentable over McFarlane et al in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Burger (5,843,91%.

McFarlane et al and Dupont et al. are applied as discussed above. The references lack anti-oxidants.

Burger teaches that vitamin E can to be added to compositions comprising glucoaminoglycan that treat arthritis, as additional components. See abstract; col. 4, lines 22-34.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to add vitamin E, as taught by Burger, into the composition of the combined references because of the expectation of achieving cells that are protected against free-radical damage and hence, are healthier.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over McFarlane et al. in view of Dupont et al. as applied to claims 1-5, 10, 13, 14-19, 22, 24, 28, 31-34 above, and further in view of Kosuge et al. (4,801,453).

McFarlane et al. and Dupont et al. are applied as discussed above. The references lack an effective amount for to provide gastro-intestinal protection.

Kosuge et al. teach compositions comprising green-lipped mussel extract for treating arthritis and gastro-intestinal irritation, conditions, lesions, and/or ulcer formation. See abstract; Col. 1, line 62-Col. 2, line 48.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach the composition of the combined references in an amount effective to provide gastro-intestinal protection because Kosuge et al. teach that compositions comprising green-lipped mussel extracts can be formulated to treat gastro-intestinal disorders or arthritis; thus, one of skill in the art would be motivated to teach an amoumt effective to provide gastro-intestinal protection because of the expectation of achieving a method of treating gastro-intestinal disorders.

Claims 1-2, 6, 15-19, 22, are rejected under 35 U.S.C. 103(a) as being unpatentable over over McFarlane et al (NZ 270754, IDS) in view of Bath et al. (6,333,304). McFarlane et al teaches an anti-inflammatory composition comprising. New Zealand green-lipped mussel extract and a fish oil, particularly useful for treating arthritis. The composition has synergistic effect as compare the individual ingredients therein. See the entire documents.

McFarlane et al. does not teach expressly a composition comprising both green-lipped mussel extract and a bark extract.

However, Bath et al. teach treatments for arthritis in animals, including non-human animals. Pine bark extract is taught as scavenging free radicals, inhibiting mast cell degranulation (cause of inflammatory response), reducing histamine release (cause of inflammatory response), and inhibiting enzymes that break down collagen and elastin, thereby stopping the deterioration of joints, and quelling inflammation. See Col. 8, lines 13-26, Col. 5, lines 24-40.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to add the pine bark extract of Bath et al. to the composition of Croft because it is obvious to combine two compositions taught by the prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose. In re Kerkoven, 205 USPQ 1069 (CCPA 1980). Additionally, it would have been obvious to add the pine bark extract of Bath et al. to the composition of McFarlane et al. because of the expectation of stopping the deterioration of the joint, quelling inflammation, and stopping free radical damage. Further, making a therapeutical composition into a well-known form, such as tablet, capsule, is within the skill of artisan. Finally, a therapeutical agent broadly known to be useful for treating arthritis, would have reasonably expected to be useful for both human and non-human animals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang
Primary Examiner
Art Unit 1617